

1. The declarations under 37 CFR 1.63 filed August 15, 2011 overcome the objection set forth in section 1 of the Office action mailed May 13, 2011.
2. The specification amendments filed August 15, 2011 have not been entered because they are not in compliance with 37 CFR 1.121(b)(1)(i) and (ii). In particular, the amendments to Paragraphs 24, 48, 52, and 53 do not provide the full text of the paragraphs being replaced. The amendment instruction for the amendment to the “Line” immediately above Paragraph 52 does not unambiguously identify the location of the paragraph being replaced, because the paragraph to be replaced occurs on plural lines above Paragraph 52. Identification of this paragraph by actual line numbers, i.e. the paragraph at page 12, lines 12-13, is preferable.

The specification amendments filed August 15, 2011 contain an underlined Sequence Listing (see pages 3-4 of Applicants’ response). Provision of, or amendments to, a Sequence Listing are not governed by 37 CFR 1.121(b) but rather are governed by 37 CFR 1.821-1.825. The paper copy of a Sequence Listing is to be submitted separately from any other part of the disclosure (see 37 CFR 1.821(c)), and is not to be underlined (37 CFR 1.121(b)(1)(ii) is inapplicable to changes to the Sequence Listing).

The claim amendments filed August 15, 2011 have been entered and considered, but they are not in compliance with 37 CFR 1.121(c)(4)(i). Claim text is presented for canceled claims 8, 19, 21, and 22, which is expressly prohibited by the rule. It should also be noted that the strikethrough provided by Applicants for these claims is incomplete, i.e. the period at the end of each claim is not struck through.

Any future amendments should be carefully reviewed for compliance with the amendment rules. Non-compliant amendments filed after final rejection will not be entered.

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reasons:

Amino acid sequences subject to the sequence disclosure rules are present in Figure 12 and at page 12, line 12, and page 13, line 4, of the specification. However, the top two sequences in Figure 12 have not been provided with SEQ ID NOS and do not appear to be listed in the Sequence Listing. With respect to those sequences in Figure 12 and in the specification now identified as SEQ ID NO:1, the disclosed amino acid sequences do not correspond with SEQ ID NO:1 as defined in the Sequence Listing.

The Sequence Listing contains new matter in its definition of the residue at position 7 of SEQ ID NO:1 and of the residue at position 1 of SEQ ID NO:2 as “any linker molecule”. The original disclosure limits this residue to “Baa”, which is defined at paragraph [0041] of the specification as “bucky amino acid”.

Applicant must provide an original computer readable form (CRF) copy of the Sequence Listing, an original paper copy of the Sequence Listing as well as an amendment directing its entry into the specification, and a statement that the content of the paper and computer readable copies are the same and include no new matter as required by 37 CFR 1.821(f) and (g).

The computer readable form copy of the Sequence Listing filed August 15, 2011 has been approved by STIC for matters of format.

4. The drawing filed August 15, 2011 is objected to because SEQ ID NOS need to be inserted after the top two amino acid sequences recited in Figure 12. See 37 CFR 1.821(d). The

amino acid sequence identified as SEQ ID NO:1 in Figure 12, also designated “fullerene peptide I” (see paragraph [0024]), is not the same as the amino acid sequence identified as Fullerene Peptide I at page 12, lines 12-13, of the specification. The sequence in the Figure comprises an additional Ile residue at its position 9. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

As an alternative to inserting SEQ ID NOS into Figure 12, it would be acceptable to insert SEQ ID NOS into the Brief Description of Figure 12 at page 4 of the specification.

5. The disclosure is objected to because of the following informalities: At paragraph [0007], line 4, “metals” is misspelled. Two different spellings of what appears to be the same word are present at, e.g., page 10, line 2 (“Fullerecine”) and at paragraph [0048], line 1 (“Fullericine”). The different spellings should be reconciled here and throughout the specification. At paragraph

[0052], line 6, and elsewhere in the specification, it is believed that “perperidine” is a misspelling for “piperidine”. SEQ ID NOS must be inserted after the amino acid sequences appearing at page 12, line 12, and page 13, line 4. See 37 CFR 1.821(d). The amino acid sequence identified as SEQ ID NO:1 in Figure 12, also designated “fullerene peptide I” (see paragraph [0024]), is not the same as the amino acid sequence identified as Fullerene Peptide I at page 12, lines 12-13, of the specification. Appropriate correction is required.

Had the specification amendments filed August 15, 2011 been in a format acceptable for entry, the objections to the disclosure originally set forth in section 4 of the Office action mailed May 13, 2011 and repeated above would have been overcome. The objection based upon a lack of correspondence between the amino acid sequence in Figure 12 and the amino acid sequence at page 12, lines 12-13, of the specification is a new objection.

6. The Sequence Listing filed August 15, 2011 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: To the extent that SEQ ID NO:1 as set forth in the Sequence Listing does not correspond with the amino acid sequences recited in Figure 12 or at page 12, lines 12-13, of the specification, the Sequence Listing contains new matter. The Sequence Listing contains new matter in its definition of the residue at position 7 of SEQ ID NO:1 and of the residue at position 1 of SEQ ID NO:2 as “any linker molecule”. The original disclosure limits this residue to “Baa”, which is defined at paragraph [0041] of the specification as “bucky amino acid”. There is no original disclosure which supports the broadened definition of this residue. Applicant is required to cancel the new matter in the reply to this Office Action.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4-7, and 9-16 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no original disclosure supporting the recitation of “a buckyketone” at claim 1, line 3. There is only a single buckyketone disclosed in the original disclosure of the invention as being useful in forming amino acids, i.e. compound 1 of Figure 1. To the extent that “a buckyketone” is intended to encompass a broader range of compounds, the genus is not supported by the single originally disclosed species. This same issue arises with the phrase “a buckyketone” at claim 10, line 4. There is no original disclosure supporting the recitation in claim 10 of a polymer comprising the general formulae, each of which comprises two terminal amine groups. A polymer formed from such monomers would be comprised of multiple hydrazine bonds, and Applicants’ original disclosure does not contain any recitation of such a polymer.

8. Claims 5-7, 12, 14-18, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is no antecedent basis in the claims for the phrase “the amino acid” at claim 5, line 2, and claim 6, line 2. Note that the independent claim uses the terminology “amino acid composition” rather than “amino acid”. To the extent that claims 5 and

6 are attempting to distinguish between an amino acid composition and an amino acid, the independent claim does not provide any basis for making such a distinction. At claim 6, line 3, the recitation “at least one of” is contradictory to the recitation at lines 1-2 that only one of the amine and carboxylic functionalities is protected. If only one of the functionalities is protected, then the amino acid/amino acid composition can not satisfy both formulae at the same time. At claim 6, line 3, the hyphen/bond sign to the right of the “OH” group should be deleted. In this general formula, it is the amine functionality which is protected, and no further modification of the OH group is possible. The reference to “and combinations thereof” at claim 12, line 3, is unclear, because no matter how peptide chains, polypeptides and/or proteins are joined together, the result is still a peptide chain, polypeptide and/or protein, i.e. the same individual members of the Markush group. At best, the recitation of “and combinations thereof” in claim 12 is redundant. The interpretation of “structure-determining” in claim 14 is unclear. Every atom in a compound necessarily contributes to the structure of the compound and is therefore “structure-determining” to at least some extent. Claim 17 is indefinite because the variable R, at line 5, third structure, and line 9, third structure, is not defined in the claim.

9. Claims 3, 17, 18, and 20 are objected to because of the following informalities: The chemical structures inserted into claims 3, 17, and 20 are illegible. Illegible portions include not only the buckyball structures but also the subscripts, the C(=O) and Me groups which are run together, and the group which is attached to the carboxy group at claim 17, line 9, first structure. Appropriate correction is required.

10. Claim 4 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the

claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Independent claim 1 has been amended to require the fullerene species to be derived from a buckyketone. However, no equivalent limitation has been added to dependent claim 4. To the extent that “fullerene” is generic to “bucky” or to “buckyballs”, then dependent claim 4 embraces fullerene species no longer permitted by the independent claim, and dependent claim 4 is an improper dependent claim. To the extent that “buckyketone” implies the buckyball structure of compound 1 in Figure 1, then dependent claim 4 is an improper dependent claim because it embraces buckyballs of different sizes as well as buckyonions and buckytubes.

11. Applicant is advised that should claim 1 be found allowable, claim 2 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof; and should claim 10 be found allowable, claim 14 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 2 appears to be identical in scope with claim 1. Because independent claim 1 has been amended to require the fullerene species to be derived from a buckyketone, necessarily the general formula recited in independent claim 1 must define buckyamino acids. Dependent claim 2 appears to recite an inherent characteristic of the claimed products of independent claim 1.

Claim 14 is identical in scope with claim 10, upon which it now depends. Every atom in a compound necessarily contributes to the structure of the compound, and therefore claim 14 merely recites an inherent property of the fullerene species required by claim 10.

12. Applicant's arguments filed August 15, 2011 have been fully considered but they are not persuasive.

Applicants did not respond to the rejection under 35 U.S.C. 112, second paragraph, of claim 12 due to the language "and combinations thereof". While claim 14 has been amended, the amendment does not appear to address the substance of the rejection under 35 U.S.C. 112, second paragraph, concerning the limitation "structure-determining".

The anticipation rejection based upon the Skiebe et al article (J. Chem. Soc. Chem. Comm., 1994, pages 335-336) is withdrawn in view of the new claim limitation "a fullerene species derived from a buckyketone". While compound 5 of the Skiebe et al article need not actually be made from a fullerene species derived from a buckyketone (see MPEP 2113), the compound must be capable of being made from a buckyketone. The examiner has not been able to find any evidence that a buckyketone can be reacted with an amine (such as is present in a lysine side chain) so as to form the amide bond present in compound 5 of the Skiebe et al article. For analogous reasons, the anticipation rejections based upon the European Patent Application 0 919 520 A2, Sagman et al (U.S. Patent No. 7,758,889), the Pantarotto et al article (J. A. Chem. Soc., Vol. 124, pages 12543-12549), and the Burley et al article (J. Org. Chem., Vol. 67, pages 8316-8330) are withdrawn in view of the new claim limitation "a fullerene species derived from a buckyketone".

The An et al article (J. Org. Chem., Vol. 58, pages 4799-4801) is cited as art of interest, teaching a buckyball linked to an amino acid via an ester group. However, the examiner can not find any evidence that the ester linkage present in the An et al article's compound is capable of

being made from a buckyketone, and therefore the reference is not deemed to anticipate or render obvious Applicants' claimed invention.

13. Claims 17, 18, and 20 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, and the claim objections set forth in this Office action.

Claim 3 would be allowable if rewritten to overcome the claim objections set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey E. Russel/  
Primary Examiner, Art Unit 1654

JRussel  
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